Brief Title: Hydroxyzine Dihydrochloride Premedication is a Necessity for Strabismus Surgery

Hydroxyzine Dihydrochloride Premedication is a Necessity for Pediatric Patients Undergoing Strabismus Surgery; An Observational Clinical Trial Controlled With Midazolam

Document Date: OCT 1, 2018 NCT NO: NCT03806270

Statistical Analysis Plan

Seventy-five pediatric patients were planned to be included to the observational study. Ramsay Sedation Score, Heart rate after anesthesia induction (KTA1), Ocular muscle name which traction will occur, Heart rate before traction (KTA2), Heart rate after traction occurred (KTA3) and OCR occurrence recorded during the study. Demographical data and the oral premedication that the participants' received were recorded after the surgery and the participants divided into three groups after the surgery related to the oral premedication they had received after the surgery.

After reaching 45 participants (15 for each group) post hoc test was done to evaluate the significance between the oral premedication utilized and the OCR occurrence, KTA1, KTA2, KTA3, and the Ramsay Sedation Score. Because there was significance in more than one groups (between oral premedication and OCR, oral premedication and KTA2, Oral premedication and KTA3) study finished before reaching the exact number of participants.

Demographic data of the participants were evaluated by minimum and maximum, mean and standard derivation.

Independent t-test, and one way ANOVA test is used for KTA1, KTA2 and KTA3 evaluation and for the relation of OCR occurrence according to the oral premedication utilized(Midazolam 0,5mg/kg only, Hydroxyzine Dihydrochloride (0,5mg/kg) plus Midazolam 0,5mg/kg, Hydroxyzine Dihydrochloride (1mg/kg) plus Midazolam 0,5mg/kg)

Chi-Square and Fisher's Exact test is used for Ramsay Sedation Score evaluation and the significance of OCR occurrence according to the oral premedication utilized.

Data evaluated as significant in 95% CI and if the p<0.05.